Relationship Between Prepregnancy Anthrax Vaccination and Pregnancy and Birth Outcomes Among US Army Women

Andrew R. Wiesen, MD, MPH
Christopher T. Littell, DO

Context Substantial concern surrounds the potential health effects of the anthrax vaccine, particularly the potential adverse effects on reproductive processes.

Objective To determine whether receipt of anthrax vaccination by reproductive-aged women has an effect on pregnancy rates.

Design, Setting, and Patients Cohort study, based on information from a computer database, of women aged 17 to 44 years who were stationed at Fort Stewart, Ga, or Hunter Army Airfield, Ga, from January 1999 through March 2000.

Main Outcome Measures Pregnancy and birth rates and adverse birth outcomes.

Results Of a total of 4092 women, 3136 received at least 1 dose of the anthrax vaccine. There was a total of 513 pregnancies, with 385 following at least 1 dose of anthrax vaccine. The pregnancy rate ratio (before and after adjustment for marital status, race, and age) comparing vaccinated with unvaccinated women was 0.94 (95% confidence interval [CI], 0.8-1.2; $P=.60$). There were 353 live births and 25 pregnancies lost to follow-up. The birth odds ratio after anthrax vaccination (before and after adjustment for marital status and age) was 0.9 (95% CI, 0.5-1.4; $P=.55$). After adjusting for age, the odds ratio for adverse birth outcome after receiving at least 1 dose of anthrax vaccination was 0.9 (95% CI, 0.4-2.4; $P=.88$). However, this study did not have sufficient power to detect adverse birth outcomes.

Conclusion Anthrax vaccination had no effect on pregnancy and birth rates or adverse birth outcomes.

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In 1970, THE ANTHRAX VACCINE WAS licensed by the US Food and Drug Administration for human use.[1] Independent civilian panels have repeatedly affirmed the safety and efficacy of the anthrax vaccine.[1-5] Until 1990, the primary recipients of this vaccine were individuals occupationally exposed to anthrax (textile mill workers, selected veterinarians, certain laboratory workers). With the advent of the Persian Gulf War, the US Department of Defense determined there was a credible threat of anthrax exposure to its troops from biological weapons and a large-scale vaccination program with anthrax vaccine was started.

Due to the persistent threat of biological weapons use, the US Department of Defense directed in 1998 that all military services begin an anthrax vaccination program.[6-9] The US military has given more than 2 million anthrax vaccinations to more than 500 000 individuals since beginning the vaccination program. Military personnel at Fort Stewart, Ga, and Hunter Army Airfield, Ga, began a program of anthrax vaccinations in the fall of 1998. Medical exemptions to vaccination were granted as clinically appropriate, the most common being deferral of vaccination during pregnancy. The program continued until March 2000, when it was curtailed because of a shortage of vaccine. After March 2000, new vaccine starts were limited to persons assigned to "high-threat" areas.

Anthrax vaccine adsorbed, distributed by BioPort Corp (Lansing, Mich), consists of aluminum hydroxide–adsorbed supernatant material, principally protective antigen, from an avirulent, nonencapsulated strain of *Bacillus anthracis*.[1,10] There is no live material in this vaccine. The vaccine series consists of 6 doses over 18 months, followed by an annual booster. Injection-site reactions (principally due to the aluminum hydroxide) have been well described.[1,4,10-13] Limited studies of long-term effects found no evidence of adverse consequences.[13,14] Although no biologically plausible mechanism for a reproductive effect has ever been proposed, this vaccine is administered to large numbers of women in their early reproductive years. Questions relating to reproductive effects are the most common concerns among callers to the US Department of Defense's anthrax toll-free information line (LTC J. D.

Author Affiliation: Department of Preventive Medicine, Madigan Army Medical Center, Tacoma, Wash. **Corresponding Author and Reprints:** Andrew R. Wiesen, MD, MPH, ATTN: MCHJ-PV (MAJ Wiesen), Department of Preventive Medicine, Madigan Army Medical Center, Tacoma, WA 98431 (e-mail: andrew.wiesen@amedd.army.mil).

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Grabenstein, RPh, PhD, USA, written communication, 2001). Because of this concern, we wished to assess whether anthrax vaccination would result in a measurable decrease in pregnancy rates. Secondary objectives were to measure effects on fetal loss and adverse birth outcomes.

METHODS

Population

The study population was US Army women aged 17 to 44 years assigned to Fort Stewart, Ga, or Hunter Army Airfield, Ga, at any time during January 1999 through March 2000. Demographic information, period of assignment, and anthrax immunization dates were obtained from local administrative and clinical databases. All outcome information (pregnancy, birth, and adverse birth outcome) was obtained from the Fort Stewart Hospital's computerized database. The study design was reviewed and approved by the institutional review board at Dwight David Eisenhower Army Medical Center, Augusta, Ga.

Outcome Measures

The primary outcome measure was pregnancy. Additional outcomes were birth following pregnancy and adverse birth outcomes. A woman was considered pregnant if a qualitative serum or urine β-human chorionic gonadotropin (hCG) test result was positive or a quantitative serum test was more than 5 IU/mL, or if she was hospitalized and discharged with an *International Classification of Diseases, 9th Revision* (*ICD-9*) diagnosis that included live birth and was assigned to Fort Stewart for at least 270 days prior to the birth. Live births included all *ICD-9* diagnosis codes of 640 to 679, but excluded those codes whose fifth digit was a 3 or 4 (admitted either for a prepartum complication without delivery or for postpartum complication without delivery, respectively). The *ICD-9* codes were used to define low birth weights (764-765) and congenital structural abnormalities (740-759). Low birth weight was defined as infants weighing less than 2500 g at birth. Structural abnormalities were defined as those abnormalities with medical or cosmetic significance. Births for women who departed Fort Stewart within 260 days of their pregnancy date without giving birth were tracked using the Defense Eligibility Enrollment System (DEERS). The only information available through DEERS was whether a birth occurred. Nonpregnant women who left Fort Stewart or Hunter Army Airfield were not tracked for pregnancy status.

Table 1. Demographic Characteristics*

	Anthrax Vaccinated (n = 3136)	Not Vaccinated (n = 962)	*P* Value
Age, median (interquartile range), y	25.6 (22.2-30.9)	25.8 (22.9-29.8)	.60
Marital status, single, %	54.2	51.8	.19
Race, %			
White	28.8	36.4	<.001
Other	19.7	12.9	<.001
Black	51.5	50.6	.59

*Six women were excluded because of incomplete data.

Predictor Variables

Anthrax vaccination status was considered positive if the woman received at least 1 anthrax immunization before the date of her positive pregnancy test result. Anthrax vaccination dates were obtained from the US Department of Army immunizations tracking database (Military Occupational Data System [MODS]). Other vaccinations required for military readiness or that were medically indicated were administered simultaneously. Age, marital status, and race, which are associated with pregnancy and birth rates (A.R.W., unpublished data, 2001),[15,16] were examined as possible confounding factors. Age and marital status were assessed at the beginning of the study period. Race was subdivided into categories of black, white, and all other, which included Hispanic, American Indian, Pacific Islander, and Asian.

Statistical Methods

A general log-linear model, using the Poisson distribution, was used to estimate rates and rate ratios for predictor variables. Model building and goodness-of-fit testing were performed using standard methods.[17] Unconditional logistic regression was used to estimate odds ratios (ORs) for birth outcome following pregnancy. Univariate comparisons were made between pregnancy occurrence and major demographic variables. Statistical analyses were performed using SPSS software, version 10.0 (SPSS Inc, Chicago, Ill). For 90% power to detect a 25% decline in pregnancy rates, assuming the fraction exposed to anthrax vaccine was 75%, the pregnancy rate was 160 pregnancies per 1000 women per year and the type 1 error held at 5% (2-sided), a total sample size of 4000 women was required. Power estimates were based on known prestudy anthrax vaccine exposure rate (47%), expected rate of rise, and previous estimates of pregnancy rates in military women (A.R.W., unpublished data, 2001). All confidence intervals (CIs) were 2-sided.

RESULTS

During the 15-month study period, 4098 women were assigned to Fort Stewart or Hunter Army Airfield. Six women were excluded because of incomplete data, leaving 4092 women eligible for data analysis; 3136 women received at least 1 dose of anthrax vaccine. There were no important demographic differences between those vaccinated and not vaccinated, except for a slight difference in racial distribution (TABLE 1). The most common reason for not being vaccinated was departure from Fort Stewart before the vaccine could be given. Persons already at Fort Stewart or Hunter Army Airfield were vaccinated as rapidly as time, training, vaccine supply, and medical resources allowed. Vaccine was

Table 2. Pregnancy Rates

Predictor	Natural Log Estimate	Relative Rate (95% Confidence Interval)	*P* Value
Age group, y			
<20	0	1.0	Referent
20-24	−0.6	0.53 (0.39-0.42)	<.001
25-29	−1.1	0.34 (0.24-0.47)	<.001
30-34	−1.8	0.17 (0.11-0.27)	<.001
35-39	−2.3	0.09 (0.05-0.17)	<.001
≥40	−3.1	0.05 (0.01-0.15)	<.001
Marital status			
Single	0	1.0	Referent
Married	0.24	1.3 (1.0-1.6)	.02
Race			
White	0	1.0	Referent
Other	−0.34	0.7 (0.5-1.0)	.02
Black	0.18	1.2 (1.0-1.4)	.07
Anthrax immunization status			
Not vaccinated	0	1.0	Referent
Vaccinated	−0.05	0.94 (0.8-1.2)	.60
Constant	−3.2	0.04 (0.03-0.05)	<.001

administered to all persons newly arrived at Fort Stewart or Hunter Army Airfield. Women were present for a median of 12 months (interquartile range, 6-15 months) and 1518 (37%) women were present for the entire 15-month period. There were 1276 new arrivals and 1387 departures prior to the end of the study period. Those who left had a lower likelihood of receiving vaccine (OR, 0.17; 95% CI, 0.15-0.20; $P<.001$) but were similar in age, race, and marital status to those remaining. There were 7464 anthrax vaccinations given during the study period. The majority of women received 2 to 3 doses during the study period (median, 2; interquartile range, 2-3; range, 1-6). The percentage vaccinated with 1 or more doses increased from 47% in January 1999 to 89% by March 2000. Persons were not allowed to defer or refuse vaccine for reasons other than bona fide medical indications (pregnancy or immune compromising disease). Pregnant women were required to be vaccinated after they gave birth or their pregnancy ended. Women who were vaccinated and then became pregnant were deferred from receiving further vaccine until they were no longer pregnant.

There were 385 pregnancies following at least 1 anthrax vaccination during 28815 person-months of follow-up time, for an annualized pregnancy rate of 159.5 per 1000 person-years. In the unvaccinated group, 130 pregnancies occurred during 9734 person-months of follow-up, for a pregnancy rate of 160.0 per 1000 person-years. The pregnancy rate ratio was 0.94 (95% CI, 0.8-1.2; $P=.60$). A general log-linear model, using a Poisson distribution, showed that age, marital status, and race were independently associated with pregnancy rates (TABLE 2). The model with the 3 predictors (age, race, marital status) was not statistically significantly different from the fully saturated model ($\chi^2_{62}=74.2$; $P=.14$). Addition of the immunization term did not improve the fit of the model ($\chi^2_{61}=74.0$; $P=.12$).

Women who received the anthrax vaccination were 1.2 times as likely to give birth as unvaccinated women (95% CI, 0.8-1.8; $P=.52$). The OR after adjustment for marital status, race, and age was unchanged (OR, 1.2; 95% CI, 0.7-1.8; $P=.53$). Eighty-five women left Fort Stewart within 260 days of their positive pregnancy test but 54 women remained eligible for medical care in the military system. Six had laboratory evidence of fetal loss prior to departing Fort Stewart. Of the 25 pregnancies lost to follow-up, 12 of the women received the anthrax vaccine and 13 did not. These women were younger, significantly less likely to have been vaccinated, and more likely to be single and white (TABLE 3). If the 488 women with at least 260 days of follow-up are considered (TABLE 4), the OR for birth and anthrax vaccination was 0.9 (95% CI, 0.5-1.4; $P=.55$). The OR after adjustment for marital status, race, and age was unchanged (OR, 0.9; 95% CI, 0.5-1.4).

Complete *ICD-9* coding data for 327 births were available for birth outcome analysis. Eleven (3.3%) of the births were of low birth weight (<2500 g). The OR for anthrax vaccination and low birth weight, after adjusting for age, was 1.3 (95% CI, 0.2-6.4; $P=.72$). There were 15 structural abnormalities of cosmetic and/or medical significance (*ICD-9* codes 740-759). No unusual patterns or clusters were noted. The only abnormality with multiple occurrences was polydactyly of the fingers (3 cases: 2 in the anthrax immunized group and 1 in the nonimmunized group). The OR for anthrax vaccination and structural abnormality, after adjusting for age, was 0.7 (95% CI, 0.2-2.3; $P=.71$). The overall OR for anthrax vaccination and any adverse birth outcome, after adjusting for age, was 0.9 (95% CI, 0.4-2.4; $P=.88$).

COMMENT

When the US Department of Defense began immunizing military personnel with the anthrax vaccine, its use was questioned by many receiving the vaccine, for only those exposed to an anthrax biological weapon would benefit. Because most would not be exposed, the attention of many service members turned to potential risks.

This is the first study to our knowledge to examine the effects on reproduction among a large group of women given the anthrax vaccine. In a previous study on pregnancy in Army women (A.R.W., unpublished data, 2001), we found a pregnancy rate of 161 per 1000 person-years in 5500 women followed up for more than 66000 person-months. When this cohort was standardized for age and race to the 1995 US population, the pregnancy rate

ratio was 1.05 (95% CI, 0.96-1.04). Furthermore, the pregnancy rate at Fort Stewart and Hunter Army Airfield during the 32 months prior to the study period was not statistically significantly different from the rate during the study (rate ratio = 1.0; 95% CI, 0.9-1.1; $P = .90$). These results do not support the hypothesis of a decrease in pregnancy rates nor an increase in fetal loss rates or adverse fetal outcome among those receiving anthrax vaccination prior to pregnancy. Although the number of adverse outcomes was small, the percentage of low-birth-weight infants was about half the expected 7.5% of low-birth-weight infants seen nationwide.[18-21] This may be due to the young age of women in our cohort. The structural abnormality rate was comparable with national rates.[22,23] This is not surprising, given the lack of a biologically plausible mechanism for any reproductive effect.

In addition, there is no evidence of infertility, miscarriages, or other reproductive problems with the use of any inactivated vaccine.[24,25] For example, tetanus, meningococcal, hepatitis B, poliovirus, and influenza vaccines are specifically recommended for susceptible women during their pregnancy.[26]

Table 3. Loss to Follow-up After Positive Pregnancy Test Result

Characteristic	Full Follow-up (n = 488)	Outcome Unknown Due to Data Censoring (n = 25)	*P* Value
Anthrax vaccinated, No. (%)	385 (78.9)	12 (48.0)	<.001
Age, median (interquartile range), y	23.5 (21.4-27.3)	21.7 (20.1-22.7)	.02
Marital status, No. (%)			
Single	294 (60.2)	21 (84.0)	.02
Married	194 (39.8)	4 (16.0)	
Race, No. (%)			
White	152 (31.1)	16 (64.0)	.003
Other	59 (12.1)	2 (8.0)	
Black	277 (56.8)	7 (28.0)	

Table 4. Odds Ratios (ORs) for Birth Following Pregnancy*

	No. of Women (%) (n = 488)	No. of Births (%) (n = 353)	Crude OR (95% Confidence Interval)	Adjusted OR† (95% Confidence Interval)	*P* Value
Anthrax vaccine					
Yes	385 (78.9)	276 (78.2)	0.9 (0.5-1.4)	0.9 (0.5-1.4)	.55
No	103 (21.0)	77 (21.8)	1.0	1.0	
Age (per additional year)			1.0 (0.96-1.05)	0.96 (0.7-1.0)	.21
Marital status					
Single	294 (60.2)	208 (58.9)	0.8 (0.5-1.2)	0.7 (0.4-1.1)	.16
Married	194 (39.8)	145 (41.1)	1.0	1.0	
Race					
White	152 (31.1)	113 (32.0)	0.9 (0.6-1.4)	1.1 (0.7-1.8)	.62
Other	59 (12.1)	43 (12.2)	1.0 (0.6-1.9)	1.0 (0.6-2.0)	.84
Black	277 (56.8)	197 (55.8)	1.0	1.0	

*Percentages may not sum to 100 due to rounding.
†Adjusted for age, race, and marital status.

This study has several strengths. First, there is the nonbiased nature of the exposure to vaccine. This military post had a blanket policy for immunization. Hence, potentially important independent risk factors, such as intent to become pregnant, use of contraceptives, marital status, age, race, and smoking status, were not related to vaccine exposure and therefore could not confound the results. There are no known medical conditions related to fertility and pregnancy that would have exempted a woman from receiving the anthrax vaccine. Second, another strength is the objectivity and completeness of the outcomes. Personnel on active military service have little opportunity to receive health care outside the military system; health care is free and testing to document pregnancy is required. Therefore, we are confident that we captured the vast majority of all pregnancies. All the medical testing at Fort Stewart is done at the installation's hospital and the results are maintained in a single computerized database. Finally, the study size provides confidence that the hypothesis regarding rate of pregnancy was not inappropriately rejected due to lack of study power.

There are several potential limitations to this study. First, there is our reliance on the accuracy of *ICD-9* coding. This is unlikely to introduce a significant bias as any miscodings would be expected to be equally distributed over both the vaccinated and unvaccinated groups. Second, we were unable to adjust for other potentially important confounders such as intent to become pregnant and smoking status. However, these were not related to the exposure to anthrax vaccine and should not confound the results. Third, it was not possible to test for dose response. The vaccine schedule calls for the first 3 immunizations to be given in the first month, then the next 3 to be given at 6-month intervals. This led to most participants receiving either 3 or 4 immunizations with insufficient numbers receiving less or more vaccine to permit a meaningful analysis of dose response. However, given the lack of overall effect, it is unlikely that a significant dose response effect is present. Fourth, there was no way to evaluate the effect of the vaccine given during pregnancy; only prepregnancy vaccine exposure was evaluated. Finally, the study does not have adequate statistical power to rule out a small effect of vaccination on adverse birth outcome, given the low incidence of adverse outcomes. A post hoc power analysis showed the study only had a 12% power to detect a 20% increase in

adverse birth outcomes, based on potential effects on likelihood of pregnancy.

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Acquisition of data, analysis and interpretation of data, and critical revision of the manuscript for important intellectual content: Wiesen, Littell.
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Love the Truth. Let others have their truth, and the truth will prevail.
—Jan Hus (c 1373-1415)